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(57) Abstract

A spray–dried powder compatible with an anhydrous or hydrophobic non–oral composition comprises a substantially water–soluble absorbent matrix containing a protein and a hydrolysed starch. Preferably the protein is obtained from plants, more preferably from seeds, most preferably from legumes. Conveniently it is an isolate from yellow peas (Pisane®). The hydrolysed starch may be maltodextrin. Preferably the powder further comprises at least one active ingredient which is incompatible with an anhydrous or hydrophobic composition when added directly. More preferably the active ingredient comprises at least one suitable pharmaceutical active ingredient, cosmetic active ingredient, toiletries active ingredient and/or any compatible mixture thereof. Most preferably the active ingredient comprises a moisturiser or a pigment. Anhydrous and hydrophobic non–oral compositions comprising the powder are described as are methods of preparing them. Preferably the compositions are suitable for topical application, more preferably they comprise a lipstick or talcum powder. The compositions may also exhibit synergistically enhanced delivery. The compositions may be used in methods of cleansing, cosmetic treatment; therapy or prophylaxis.

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SPRAY-DRYED POWDER COMPRISING AT LEAST ONE PROTEIN AND ONE HYDROLYSED STARCH AND ITS USE FOR TOPICAL COMPOSITIONS

The invention relates to anhydrous and hydrophobic compositions for non-oral use, to methods of preparing such compositions, to methods of using such compositions. Such compositions comprise a novel powder and have advantageous and unexpected properties over the prior art.

Anhydrous compositions are substantially free of free-water. Hydrophobic compositions do not substantially mix with aqueous or hydrophillic compositions. Hydrophobic compositions may comprise water if their continuous phase is substantially non-aqueous or oily (e.g. a water-in-oil emulsion). Both anhydrous and hydrophobic compositions have the disadvantage that they are incompatible with many useful ingredients which are miscible with or solvated by aqueous media. It would be advantageous to be able to formulate with a wider range of ingredients in such compositions. It is an object of the invention to solve at least some of the above problems with the prior art compositions.

The applicant has developed a new powder which overcomes some or all of the preceding disadvantages when incorporated into anhydrous and/or hydrophobic compositions.

Spray-drying is a technique which has been used mainly in the food industry to produce powder from liquid compositions. The composition to be spray dried is atomised into small droplets, and fed into the top of a tall tower through which hot air is passed (typically at 180°C to 250°C). The more volatile components of the composition evaporate. As the droplets fall through the tower the temperature drops and they condense to produce small particles. The particles are separated and collected by a suitable method (e.g. in a cyclone).

Spray-drying typically produces fine, uniform powders of small, hollow-cored particles.

Other similar techniques to spray-drying include freeze-drying and vacuum drying. To freeze-dry a composition it is cooled until it solidifies and placed under reduced pressure to cause the most volatile ingredients in the composition to sublime. The solid residue may form a single mass which requires milling to form a fine powder. A typical freeze-dried powder comprises porous irregular shaped particles and readily hydrates. As freeze-drying does not require strong heat it is used to produce powders which comprise volatile ingredients (e.g. instant coffee granules). The drawback of powders produced by freeze-drying over spray-drying is that they are about double the cost due to the extra complexity of the freeze-drying process (e.g. equipment to operate at reduced pressures).

Vacuum drying is a similar technique to freeze-drying in which the composition remains at ambient temperature when it is under reduced pressure.

Spray-drying is the preferred technique to produce the powder of the invention although it may be possible to produce this powder by freeze-drying or vacuum-drying. The terms "spray-drying" and "spray-dried" are used herein for simplicity but the skilled person will appreciate that freeze-drying and vacuum drying can be substituted for spray-drying as appropriate.

Foodstuffs have been prepared by spray-drying but the technique has not been widely used to prepare topical compositions such as cosmetic or toiletries formulations. This is because there was little advantage perceived in spray-drying topical compositions and the specialised equipment required was expensive.

Various spray-dried anti-perspirant actives are components of known anhydrous anti-perspirant products. Such anti-perspirants are disclosed in (amongst others): US 5135741 (Chesebrough Ponds); US 5114705 (Gillette); EP 0405598 (Dow Corning); and GB 1534861 (Wicks). These spray-dried anti-perspirant powders comprise compounds such as aluminium chlorohydrate and zirconyl hydroxychloride which are highly charged.

Compounds with a high ionic charge could not be spray-dried with the water-soluble matrices used in the powders of the applicant's invention and the above prior art teaches away from this invention. However after spray-drying the powders of the invention would be compatible with such compounds. Therefore compositions of the invention may comprise anti-perspirant active ingredients if such ingredients are not in the spray-dried powder.

JP 60-042317 (Hikiyo) describes the spray-drying of oily ingredients to form a powder for incorporation into an aqueous composition to remove the need for emulsifiers in the resultant composition.

South Korean patent application KR 92-05639 (Pacific Chemical) discloses a spray-dried material prepared from a biologically active ingredient. This ingredient is dissolved in an agar solution with a phospholipid to form, after spray-drying, a liposome of 1-500 microns which can be added to make up. The phospholipid is not a water soluble matrix as used in the powders of the present invention.

JP 61-030508 (Nippon Oils & Fats) describes an emulsion of a squalane compound coated with gum arabicum, carraginan, sodium arginate or carboxymethyl cellulose and optionally a surfactant which is spray-dried to form a powder which is used as a cosmetic substrate optionally as an anti-bacterial or anti-fungal agent.

JP 52-69187 (Suntory) describes a spray-dried powder formed from a mixture of dextrin, gum arabic or carboxymethylcellulose (CMC) with an extract of Tencha (a Chinese hydrangea). The powder may be used in foods or cosmetics and has a deodorising effect against compounds comprising S-H bonds.

DD 112351 (Neuman) discloses a spray-dried complex dermatologically active principle consisting of the proteins (e.g. whey protein), vitamins and salts contained in milk, the powder being for use in cosmetics.

Food Ingredients - Processing International (14 October 1991) discusses certain special starches as alternatives to arabic gum as a fat binder and emulsifier in foodstuffs, such starches optionally being spray dried.

Food-Prod-Des 1993 2(10), 67-68 describes use of certain gum arabic products as carriers to replace food starch for spray dried flavours. (it is not clear whether the gum is also spray dried).

None of the preceding documents suggest addition of spray-dried powder comprising a water soluble matrix to anhydrous or hydrophobic non-oral compositions.

The new spray-dried powder of the invention has unusual and surprising properties useful to a formulator of anhydrous and hydrophobic non-oral compositions especially those for topical use. The material can be advantageously incorporated in such compositions to enhance their properties.

The spray-dried powder comprises a water-soluble absorbent matrix optionally mixed with at least one active ingredient. The powder may also comprise ingredients which are incompatible with anhydrous or hydrophobic compositions when added directly. Compositions with this powder exhibit desirable properties

such as improved skin-feel. Surprisingly the powder of the invention also provides the additional unexpected advantage of synergistically enhancing the delivery of compositions to which it is added.

Therefore one aspect of this invention comprises a spray-dried powder which is compatible with an anhydrous and/or hydrophobic non-oral composition, the powder comprising a substantially water-soluble absorbent matrix containing at least one protein and at least one hydrolysed starch. Preferably the powder is suitable for topical delivery. Preferably the water-soluble absorbent matrix is hygroscopic and can be rapidly rehydrated.

The term 'non-oral composition' denotes any composition which is in a form suitable for administration to the body by any route other than solely the oral route (i.e. via the mouth). It includes compositions applied topically near to the mouth or on the lips (e.g. lipsticks).

The water-soluble absorbent matrix comprises a mixture of at least one protein and at least one hydrolysed starch in which the ratio by weight of protein to hydrolysed starch lies in the range 1:20 to 1:2 preferably 1:10 to 1:4.

Preferred proteins include plant protein, casein and its salts (e.g. sodium caseinate) and mixtures thereof. Preferably the protein is obtained from plants, more preferably seeds, most preferably legumes. The protein may be a concentrate (at least about 70% protein), preferably an isolate (at least about 90% protein). More preferably, the protein is obtained from beans (e.g. soya beans and/or broad beans) and/or peas (e.g. yellow peas). Most preferably the protein comprises protein isolated with high purity (at least about 90% protein on at least about 95% dry matter) from the kernel of yellow peas, such as that available commercially from Cosucra in Belgium under the trade mark 'Pisane' ®. The average amino acid content (expressed as relative proportions of mass) in the Pisane ® protein is approximately as follows: glycine 4.3;

alanine 4.6; valine 5.1; leucine 8; isoleucine 4.7; serine 5.3; threonine 4; tyrosine 4; aspartic acid 12; phenylalanine 5.3; tryptophan 0.9; proline 4.5; methionine 0.93; cysteine 1; lysine 8.2; histidine 2.8; arginine 8.9; and glutamic acid 18.5.

The protein (such as highly concentrated or isolated protein fractions) may be prepared by known techniques such as wet processing, for example separation by solubilization of matrix followed by isoelectric precipitation for subsequent recovery. Other suitable known separation processes for extracting proteins comprise 'salting-out', 'hydrophobic-out' and ultrafiltration.

The hydrolysed starch preferably has a molecular weight in the range 1,000 to 100,000 and is readily soluble in water. Suitable hydrolysed starch include maltodextrin, hydrolysed potato derivative, hydrolysed corn derivative, hydrolysed maize derivative, hydrolysed oat derivative, hydrolysed tapioca derivative, cyclodextrin, dextrin (from corn, tapioca etc), pullulan and cellulose derivatives such as ethyl cellulose dispersion. A preferred hydrolysed starch is maltodextrin having a molecular weight in the range 1,000 to 10,000.

The powder of the invention may be formed by spray-drying any suitable liquid containing the matrix. The liquid to be spray-dried may be in the form of a solution, emulsion, dispersion or suspension. The liquid preferably comprises water as a carrier material though any liquid which can be removed during spray drying can be used as the carrier material. The amount of water should be the minimum needed to ensure that the components of the liquid feed to the spray drier are intimately mixed and to ensure that the liquid can be efficiently sprayed into the spray drier. Other components which are intended to be incorporated into the spray dried powder may be dispersed, dissolved or suspended in the carrier material. Examples of such materials include oils (eg vegetable, mineral or silicone oils), emulsifiers, thickeners (eg xanthan gum or carboxymethylcellulose), moisturisers (eg 1,3-butyleneglycol), active ingredients

to be more fully described hereinafter, organic sunscreens such as octylmethoxycinnamate and inorganic sunscreens such as titanium dioxide. The liquid may also comprise ingredients which are incompatible with an anhydrous or a hydrophobic composition when added directly to it, but which can be incorporated into the composition using the spray dried powder of the present invention. The liquid to be spray-dried is substantially free of any ingredient which is incompatible with the matrix. Such incompatible ingredients may comprise: species which are substantially non isoelectric with the matrix (for example species with a very high ionic charge [such as highly polyvalent ions] and/or compositions with a very low or high pH); enzymes which will attack the matrix (such as proteinases and/or amylases); and ingredients which will cause flocculation. If the mixture to be spray-dried comprises an aqueous composition preferably it has a pH of at least about 5 (more preferably between about 6 to about 7) as at a lower pH the matrix is more likely to be insoluble. If the liquid to be spray-dried comprises an aqueous carrier, the liquid may further comprise pH adjusting agents such as sodium hydroxide, aminomethyl propanol, triethanolamine, suitably in an amount of from about 0.01% to about 10% by weight of the composition. Such compositions may be buffered by means well known in the art, for example by use of buffer systems comprising succinic acid, citric acid, lactic acid, and acceptable salts thereof, phosphoric acid, mono- or di-sodium phosphate and sodium carbonate. A suitable pH may be between about 3 and about 10, preferably between about 4 and about 8, more preferably about 6. Preferably the matrix is isoelectric with the liquid to be spray-dried.

If the liquid to be spray-dried comprises an oil-in-water emulsion it may comprise from about 5% to about 60% by weight of an oil phase, from about 1% to about 20% by weight of an emulsifier or a mixture of emulsifiers and at least about 35% by weight of an aqueous phase.

Suitable oils for inclusion in the spray dried powder include vegetable oils such as wheatgerm oil, mineral oils such as paraffin oils or silicone fluids. Mixtures of oils may be used. The oils may be incorporated into the liquid to be spray dried as the oil phase of a water-in-oil emulsion. The oils may comprise 15 to 50%, preferably 20 to 40%, by weight of the spray dried powder. The inclusion of oils in the powder of the present invention provides powders for inclusion in cosmetic and toiletries formulations which act as moisturisers. The use of the powders of the present invention containing such oils enables moisturising oils to be incorporated into compositions into which it would be difficult or impossible to incorporate such oils directly.

Once the liquid has been spray-dried the resultant powder is compatible with many ingredients which would have broken down the matrix during spray-drying.

The spray-dried powder may comprise one or more surfactants (emulsifiers). Preferably, the surfactant comprises from about 1% to about 10% by weight of the powder. Suitable surfactants (which may also act as an emulsifier if necessary) include salts of alkyl ether sulphates; alkyl betaines; alkylamidoalkyl betaines; polyethyleneglycol carboxylates; salts of alkyl sulphates (such as ammonium lauryl sulphate); sulphosuccinates (such as disodium laureth sulphosuccinate); amphomonoacetates and diacetates (such as disodium cocoamphodiacetate); alkylpolyglucosides; alcohol sulphonates; ethoxylated fatty alcohols; ethoxylated fatty acid esters (such as ethoxylated stearates); sorbitan esters; ethoxylated sorbitan esters; silicon emulsifiers (such as silicone polyols); anionic emulsifiers (such as cetylstearyl sulphates and anionic esters of mono and diglyercides); cationic emulsifiers; fatty acid soaps (such as potassium stearate); ethoxylated mono-, di-, and tri-glycerides; phospholipids (such as lecithin); and sorbitan monooleate and mixtures thereof.

The spray-dried powder optionally contains an active ingredient. Suitable active ingredients are those which would be incompatible with anhydrous or hydrophobic compositions when added directly to such compositions. When compositions of the invention are applied topically, water in the environment (for example humidity in the atmosphere, moisture on the skin or saliva on the lips) may re-hydrate the spray dried powder to activate any active ingredients to provide their additional properties (e.g. moisturising) to the composition.

The active ingredient comprises any ingredient which is compatible with the water-soluble absorbent matrix and which has an action on the body when administered thereto and comprises at least one suitable pharmaceutical active, cosmetic ingredient, toiletries ingredient and/or any compatible mixture thereof. The active ingredient may perform more than one function falling into one or more of the preceding categories. Preferably the active ingredient is present in an effective amount. Preferred active ingredients comprise compatible pharmaceutical, cosmetic and/or toiletries ingredients which may be medicated or unmedicated.

A pharmaceutical active ingredient comprises any pharmaceutically acceptable, physiologically active ingredient (including mixtures) which is suitable for non-oral application to a patient in need thereof. This includes all suitable physiologically active compounds, acceptable derivatives thereof (such as salts) and prodrugs (ingredients that are metabolised in vivo to give physiologically active species). The pharmaceutical active may be used to treat (by therapy and/or prophylaxis) clinical conditions (including any disorders and/or diseases) in a patient (including humans) in need thereof whether by localised application to a particular site and/or generalised systemic application.

A cosmetic active ingredient comprises any ingredient (including mixtures) which when applied will alter and/or enhance appearance. Preferred cosmetic ingredients which may be incorporated into the powders and compositions of

the invention have pigmentary and/or moisturising properties when applied topically to normal human skin or lips. Suitable moisturisers include D-panthenol and 1,3-butylene glycol. Suitable pigments comprise various inorganic and organic pigments which are preferably powders. Suitable inorganic pigments, especially for use in lipsticks, comprise iron oxides, ultramarines and titanium dioxide. Pigments may further comprise inorganic pigments that give a pearly finish, for example bismuth oxychloride and titanium dioxide coated mica. Suitable organic pigments, especially for use in lipsticks, comprise various suitable aromatic components including monoazo, indigoid, fluoran and pyrazole dyes. Pigments are selected to be cosmetically acceptable and to comply with the laws and regulations of the territories in which they are to be used. For example in the European Union at the priority date of this application, suitable pigments are those listed in Annex IV of the Cosmetics Directive 76/768 EEC.

A toiletries active ingredient comprises any suitable ingredient (including mixtures) which is used for the purpose of personal hygiene and/or when applied, preferably topically, has a cleansing action on the body.

The spray-dried powder of the invention may also be surface-treated with suitable agents (such as aluminium stearate, amino acids, mineral oils, phospholipids, silicone oil and/or mixtures thereof) which coat the powder surface, render the particles hydrophobic in nature, prevent agglomeration and/or aid dispersion of powder within a composition.

A further aspect of the present invention comprises a substantially anhydrous and/or hydrophobic composition suitable for non-oral application which comprises a spray-dried powder as described herein. Preferably the composition is suitable for topical application. The composition may contain 0.1 to 60% of the spray dried powder by weight. The composition may be a pharmaceutical, cosmetic and/or toiletries composition. Examples of such

compositions include (a) powder compositions such as pressed powder cosmetics, bath salts, foot powder, talc or eyeshadows, (b) shaped solid compositions such as lipsticks, soaps, deodorant sticks, sunscreen sticks or eye pencils, (c) nail enamels or nail lacquers. Powder compositions may contain up to 60% preferably 1 to 50%, more preferably 10 to 50% of the spray dried powder. Shaped solid components may contain up to 10% preferably 0.5 to 5% more preferably 1 to 3% of the spray dried powder. Nail enamels or lacquers may contain up to 5% preferably 0.1 to 3%, more preferably 0.25 to 2% of the spray dried powder.

The applicant has surprisingly discovered that the powder of the invention can act synergistically with other ingredients in such compositions to enhance the delivery, preferably topically delivery, of the composition and/or any active ingredients therein. This improved delivery is a unexpected further advantage of compositions of the invention. For example when the composition comprises a pigmented lipstick there is enhanced delivery of colour to the lips. Data to illustrate the synergistically enhanced topical delivery of compositions of the invention are provided in the Examples.

Compositions which deliver more composition per application (e.g. topically when applied to the skin) have an enhanced effect. Alternatively reduced quantities of ingredients are require to achieve the same effect. Thus money may be saved on raw materials, undesirable effects of any ingredient may be reduced and less potent ingredients can be substituted. If less active ingredient can be used this also allows compositions to be applied to sensitive sites on the body.

Pharmaceutical compositions comprise the spray dried powder containing a therapeutically and/or prophylactically effective amount of at least one pharmaceutical active ingredient with a pharmaceutically acceptable and compatible diluent or carrier.

Cosmetic compositions comprise the spray dried powder containing an effective amount of at least one cosmetic ingredient together with a cosmetically acceptable and compatible diluent or carrier. Preferably the cosmetic composition comprises powders (e.g. talcum powder, face powder, and/or foot powder), sunscreens, make-ups (e.g. concealers, blushers, eye-shadows, eyebrow pencils, eye pencils, mascaras, foundations, nail lacquers, sunsticks, chapsticks and / or lipsticks) and/or any other suitable compositions (such as anti-perspirants and/or deodorants [e.g. in the form of a stick]).

Nail lacquers include nail varnishes, top coats, base coats, nail hardeners and ridge fillers.

Lipsticks may be medicated or unmedicated and comprise lip salves; lip balms; lip glosses; solid compositions to treat sore, cracked and/or split lips; and/or pigmented sticks which colour the lips. The choice of colour or shade is a very important consideration for the consumer when purchasing any pigmented cosmetic, especially a lipstick. Consumers demand a wide choice of colours and shades. However more intense shades and colours can be difficult to produce due to the difficulty of formulating compositions with high concentrations of pigment. This is because homogeneous dispersions of large amounts of pigment in an oil can be unstable. Also large concentrations of pigment may have a greater potential for allergic reaction on the skin. The invention provides lipsticks which can deliver more pigment to the skin to provide new, more intense shades of colour. Alternatively less pigment can be used to produce a known colour shade which both saves money and reduces the possibility of unwanted bleeding of colour away from the site of application. This is especially useful for lipsticks as pigment can be more readily retained on the lips reducing unsightly spread of colour onto the skin adjacent to the lips. Lipsticks may further comprise one or more cosmetically acceptable additional ingredients suitable for lipsticks selected from: gloss modifiers, texture

modifiers, moisturising agents, soothing agents, conditioners, vitamins and/or sunscreens.

Sunscreens encompass tanning lotions, sunscreens and sunblockers which are intended for use on the body to provide protection against the sun's rays or other UV sources. Sunscreen agents which may be incorporated into the compositions of the present invention comprise organic chemical agents which act to absorb incident UV radiation and/or inorganic sunscreen agents which act to reflect incident UV radiation. Examples of suitable sunscreening agents comprise one or more of the following or any suitable mixtures thereof: p-aminobenzoic acids, esters and derivatives (e.g. octyl-p-dimethylaminobenzoate); methoxycinnamate esters (e.g. 2-ethylhexyl-p-methoxycinnamate, or 2-ethoxyethyl-p-methoxycinnamate); benzophenones (for example oxybenzone); dibenzoylmethanes; salicylate esters; metal oxide sunscreens (such as TiO_2, preferably of having mean primary particle size between 1 to 100 nm, or ZnO preferably having a mean primary particle size between 30 and 300nm or any mixture thereof) . Preferably any sunscreening agent is present in an amount from about 0.1% to about 25%, more preferably 0.5% to 15% by weight of the composition.

The percentage of pigment used in a cosmetic composition will depend upon the type of cosmetic being formulated. Blushers, eyeshadows, mascara, lipsticks and similar cosmetics will contain higher percentages of pigment than other cosmetics. Lipsticks and other highly coloured compositions may contain up to 15% w/w of pigment by weight of the composition. Powder compositions may contain up to 5% w/w of pigment by weight of the composition.

Cosmetic compositions of the invention (for example lipsticks) may comprise one or more oil components, one or more wax components and/or one or more additional powder components. Preferably the cosmetic compositions contains from about 30% to about 85% w/w of the oil component; from about 1% to

about 40% w/w of the wax component; and from about 1% to about 40% w/w of the additional powder component.

The oil component may comprise one or more cosmetically acceptable oils, silicones, fats and/or any mixture thereof. Suitable cosmetically acceptable oils comprise natural oils (for example plant oils [such as almond oil, vegetable oil and castor oil]), synthetic esters (for example pentaerythrityl tetracaprylate and pentaerythrityl tetraisostearate), fatty oils (for example triglyceride esters), fatty alcohols (for example oleyl alcohol and octyldodecanol) and mineral oils (for example liquid paraffin and C_{11-12} isoparaffin). Suitable cosmetically acceptable silicones may comprise volatile silicones (for example volatile linear polydimethylsiloxanes) and cyclomethicone and non-volatile silicone oils (for example phenyldimethicone). Suitable cosmetically acceptable fats may comprise natural fats (for example animal fats [such as wool fat], vegetable fats [such as triglyceride esters] and mineral fats [such as white soft paraffin]) and synthetic fats (for example bisdiglyceryl caprylate / caprate / isostearate stearate / hydroxystearate adipate). Preferably the oil component is present in an amount from about 50% to about 80% w/w. Optionally the oil component may further comprise soothing agents (for example alpha bisabolbol, a plant extract, such as camomile extract and/or moisturising agents (for example an alkylene glycol [such as butylene glycol]).

The wax component preferably has a melting point in the range from about 30 °C to about 120 °C. Suitably the wax component comprises one or more cosmetically acceptable waxes, wax-like materials and/or any mixture thereof. Suitable waxes comprise natural waxes (for example plant waxes [such as candelilla wax, carnauba wax, castor wax and illupe butter], animal waxes [such as beeswax, lanolin wax, lanolin derivative waxes and white wax] and mineral waxes [such as ozokerite wax, montan wax and paraffin waxes {e.g. microcrystalline wax, okerin wax and paraffin}]), synthetic waxes (for example hydrogenated castor oil and cetyl alcohol) and silicone waxes (for example

C_{24-28} alkyl methicone). Preferably the wax component is present in a cosmetic composition in an amount from about 5% to about 40% w/w, more preferably from about 10% to about 30% w/w.

Preferably, the additional powder component is present in an amount from about 2% to about 30% w/w. If the cosmetic composition is a lipstick, the additional powder component may comprise a dry, particulate material having a mean primary particle size from about 0.02 microns to about 80 microns. Particle size is measured along the longest axis of the particle. The additional powder component may comprise pigmentary powder and/or non-pigmentary powder. Suitable pigmentary powders comprise various inorganic and organic pigments such as those described herein. Suitable non-pigmentary powders comprise acrylate polymers, alumina, aluminium silicate, bentonite, boron nitride, calcium carbonate, calcium silicate, cellulose, corn starch, kaolin, magnesium aluminium silicate, magnesium carbonate, mica, micronised Teflon ® (PTFE), nut shell powder (such as walnut shell powder), nylon, polyethylene, polymethyl methacrylate beads, silica, silk powder, tin oxide, zinc myristate and any mixtures thereof.

Preferred topical cosmetic compositions of the invention are lipsticks and talcum powders. Particularly preferred anhydrous and/or hydrophobic topical compositions of the present invention comprise:

a talcum powder further comprising a spray-dried powder of the present invention with a moisturiser as an active ingredient; and

a lipstick further comprising a spray-dried powder of the present invention with a suitable pigment and/or moisturiser as an active ingredient.

Toiletries compositions comprise the spray dried powder containing an effective amount of at least one toiletries ingredient with a topically acceptable and compatible diluent or carrier. Preferred toiletries compositions include bubble baths, shower gels, bath salts, hair-care compositions and/or soaps.

Hair-care compositions include so-called "hot oil" treatments, shampoos, conditioners, hair dyes, mousses, foams, gels, creams, waxes, masks, muds, styling sprays, lotions and rinses, all suitable for use preferably on humans, most preferably on the human head. Hair-care compositions may also include an anti-dandruff agent such as salicylic acid or zinc pyrithione suitably in an amount of from about 0.1% to about 5% by weight of the composition.

Compositions of the invention may be administered topically, which is the preferred route of administration. If appropriate topical compositions may comprise a further matrix in which the spray-dried powder is dispersed to facilitate transdermal administration of active ingredients when the composition is held in contact with the skin. Active ingredients may also be delivered transdermally from topical compositions by electrotransport and/or iontophoresis. The amount of active ingredients in the topical composition should be such that an amount of the ingredient which will be sufficiently effective for the intended purpose will be delivered during the period of time which the topical composition is intended to be on the skin.

Suitable topical compositions for transdermal administration of an active ingredient may be prepared by mixing and/or dispersing the spray-dried powder with the active ingredient in anhydrous and/or hydrophobic topical vehicles together with suitable potential transdermal accelerants (such as dimethyl sulphoxide and/or propylene glycol). Topical vehicles may comprise any suitable foam, paste, salve, lotion, cream, ointment, oil, emulsion and/or gel base; and/or compositions suitable for application as a spray and/or aerosol. Topical vehicles may also comprise topical delivery devices such as cataplasms, poultices, patches and/or impregnated bandages. Topical compositions suitable for transdermal administration may also be held in an optional carrier which may be dissolved and/or dispersed in an adhesive and/or polymer base (for example on a patch).

Suitable creams for topical application may be prepared by incorporating the spray-dried powder of the invention in petrolatum and/or light liquid paraffins which are then dispersed in non-aqueous media optionally using surfactants. Ointments may be prepared by mixing the powder with mineral oils, petrolatum and/or waxes (for example paraffin wax and/or beeswax). Gels may be prepared by mixing the powder with gelling agents in the presence of a suitable non-aqueous solvent and/or optionally a base. Clear gels may comprise clarifying agents (for example denaturated alcohols [such as denaturated ethanol]).

Topical compositions of the invention may also comprise ionic or non-ionic surface active agents to promote greater effectiveness (e.g. improved therapeutic and/or prophylactic activity) in the compositions if applied topically. The surface active agents may also comprise emulsifying ingredients and/or surfactants even if the compositions are not emulsions.

Topical compositions of the invention may additionally comprise further components well known to those skilled in the art and which are suitable and directly compatible with an anhydrous and/or hydrophobic composition. Such ingredients may comprise any of the optional ingredients as described herein and/or any suitable and compatible mixtures thereof.

Compositions of the invention that have a high lipid solubility may be suitable for use in so-called depot formulations which provide a source of active ingredient located within the body (for example by intra-muscular injection). Depot formulations may comprise active ingredients in a pharmaceutically acceptable oil.

In some formulations it may be beneficial to use powders and/or compositions of the invention in the form of particles of very small size, for example as obtained by fluid energy milling. Alternatively the powder and/or active

ingredient may be bound (for example by sorption, incorporation and/or chemically) to nanoparticles which are collodial polymeric particles of a size typically less than 1 micron. The distribution of such nanoparticles in the body and hence the sites of delivery of the active ingredient can be effected by coating the surface of the nanoparticles appropriately (for example with surfactants and/or antibodies).

Compositions of the invention may be solid or fluid (including free-flowing powders and/or granules and non-aqueous liquids). A non-aqueous liquid comprises a liquid in which the continuous phase is substantially free of free-water such as an oil or an water-in-oil emulsion. Compositions of the invention which are solid at ambient temperature may be compressed in the form of a stick and/or incorporated into anhydrous sticks (e.g. hot wax sticks) or extrudates. Fluid compositions of the invention which comprise a free-flowing powder may be applied by means of a suitable implement (for example a make-up brush). Liquid compositions of the invention may be dispensed from a suitable container (for example from a squeezable tube though a nozzle).

Acceptable diluents and/or carriers suitable for compositions of the invention are well known to a skilled formulator. The excipients used in the preparation of such compositions are the excipients known in the formulator's art.

Solid compositions of the invention may be prepared by mixing the spray-dried powder of the invention with one or more of the following ingredients which are acceptable in a solid anhydrous and/or hydrophobic composition: inert diluents, lubricating agents, binders and/or any mixtures thereof. It will be appreciated by those skilled in the art that a particular ingredient may perform more than one function (for example maize starch may act as a diluent, binder and/or disintegrating agent).

Inert diluents may comprise sugars (for example lactose, dextrin, sucrose, mannitol, powdered sugar and/or mixtures thereof), celluloses (for example microcrystalline cellulose), starches (for example maize starch, other pharmaceutical grade starch and/or mixtures thereof), clays (for example kaolin and/or hectorite), calcium phosphate, calcium sulphate and/or mixtures thereof.

Lubricating agents may comprise magnesium stearate, calcium stearate, stearic acid, talc, paraffin sulphate, boric acid, sodium benzoate, sodium acetate, sodium chloride, leucine, polyethylene glycol and/or mixtures thereof.

Binders may comprise starches (for example maize starch), gelatin, sugars (for example sucrose, molasses, lactose and/or mixtures thereof) and/or natural and/or synthetic gums (for example acacia, sodium alginate, extract of Irish moss, celluloses [such as carboxymethylcellulose, hydroxypropylmethyl cellulose, methylcellulose, ethylcellulose, microcrystalline cellulose and/or mixtures thereof], polyethylene glycol, waxes, polyvinylpyrrolidone and/or mixtures thereof).

Solid compositions of the invention may further comprise one or more of the following acceptable ingredients and/or mixtures thereof that are known to aid production of solid compositions:-

agents to aid the flow of ingredients (for example talc and/or colloidal silicon dioxide);

compression agents to increase the strength of a solid composition (for example sorbitol and/or lactose); and/or

ionic and/or non-ionic surface active agents (for example sodium lauryl sulphate) to promote an even dispersion of ingredients within a solid composition and prevent grit forming at the surface.

Preferably solid compositions of the invention are shaped to be more convenient for general use, for example in stick form.

Fluid compositions of the invention may be formulated into granules and/or powders with or without additional excipients. Such compositions may be free-flowing powders prepared from dry products and may be used directly, or before use they may be added to suitable fluid carriers (e.g. to reconstitute or a liquid composition of the invention).

Liquid compositions of the invention may comprise elixirs, emulsions, solutions, syrups and/or suspensions which contain the spray-dried powder in a suitable non-aqueous medium. Certain of the liquid compositions described herein may also be suitable for spray-drying with the water-soluble absorbent matrix to form a powder of the invention (in which case such liquids may also comprise free-water). Liquid compositions of the invention may comprise suitable oily suspensions, oily solutions and/or water-in-oil emulsions.

Acceptable solvents for liquid compositions of the invention comprise glycol, oils and/or alcohols. Media suitable for preparing syrups and/or suspensions may comprise oily media and/or emulsions in the presence of one or more pharmaceutically acceptable suspending agents (for example aluminium stearate gel, cellulose [such as methylcellulose, hydroxyethylcellulose and/or sodium carboxymethylcellulose] gelatin, hydrogenated fats and/or sorbitol). Suitable oily media may comprise vegetable oils (for example arachis oil and/or sunflower oil), other edible oils (for example almond oil and/or fractionated coconut oil) and/or oily esters (for example esters of glycerine, propylene glycol and/or ethanol).

Liquid compositions of the invention which are oily may comprise one or more of the following and/or any suitable mixtures thereof: hydrocarbon oils such as paraffin or mineral oils; waxes such as beeswax or paraffin wax, natural oils such as sunflower oil, apricot kernel oil, shea butter or jojoba oil; silicone oils such as dimethicone, cyclomethicone or cetyldimethicone; fatty acid esters

such as isopropyl palmitate or isopropyl myristate; and fatty alcohols such as cetyl alcohol or stearyl alcohol.

Liquid compositions of the invention may further comprise one or more of the following which are acceptable and compatible with anhydrous and/or hydrophobic compositions: agents which vary osmotic pressure (for example salts); colouring agents; agents which adjust the equivalent of pH in non-aqueous systems (for example buffers); and/or mixtures thereof.

Liquid compositions of the invention, suitable for topical use, may further comprise resins, such as one or more of the following, and suitable mixtures thereof: octylacrylamide / acrylates / butylaminomethacrylate copolymer (available under the trade name Amphomer); ethyl ester of polyvinylmethyl (hereinafter known as PVM) / methylacrylate (hereinafter known as MA) copolymer (available under the trade name Ultrahold 8A); vinyl acetate (hereinafter known as VA) / crotonates / vinyl neodecanate copolymer (available under the trade name Adhesive 28-2930 NAL); acrylates / acrylamide copolymer (available under the trade name Gantrez ES225); vinyl acetate / crotonic acid / vinyl propionate copolymer (available under the trade name Luviset CAP); polyvinylpropionate (hereinafter known as PVP) / VA / vinylpropionate copolymer (available under the trade name Laviskol VAP); octylacrylamide / acrylate copolymer (available under the trade names Versatyl 90 or Lovocryl 47); vinyl caprolactam / PVP / dimethylaminoethyl methacrylate copolymer (available under the trade name (H_2O LD EP-1); PVM / MA copolymer (available under the trade name Gantrez); and vinyl acetate / butyl maleate / isobornyl acrylate copolymer (available under the trade name Advantage CP). The resins may be present suitably in an amount of from about 0.1% to about 10% by weight of the composition.

Liquid compositions of the invention, suitable for topical use, may further comprise slip aids such as phenyl trimethicone, suitably in an amount of from about 0.1% to about 10% by weight of the composition.

If the composition of the present invention comprises a water-in-oil emulsion, it may comprise from about 5% to about 70% by weight of an oil phase, from about 1% to about 15% by weight of an emulsifier, and at least about 20% by weight of a dispersed aqueous phase. The oil phase may comprise any suitable mixtures of oily ingredients such as those described herein. In preferred water-in-oil emulsions of the invention the oil phase comprises from about 5% to about 60% by weight of the composition. In particularly preferred oil-in-water compositions of the present invention, the oil phase comprises from about 10% to about 30% by weight of the composition. The emulsifier or mixture of emulsifiers may be selected from known cosmetically acceptable emulsifiers. In preferred compositions of the invention the amount of emulsifier present in these emulsions is from about 1% to about 10% by weight of the emulsion.

Other components that may be appropriately added to compositions of the invention to those skilled in the art. Such ingredients may comprise at least one of the following and any suitable and compatible mixtures thereof (some ingredients may perform more than one function):

preservatives such as 2-bromo-2-nitropropane-1,3-diol (bronopol, which is available commercially under the trade name Myacide), benzyl alcohol, diazolidinyl urea, imidazolidinyl urea, methyl paraben, phenoxy ethanol, polyhexamethylenebiguanide hydro-chloride, isothiazolone, sodium dehydro-acetate, propyl paraben, sodium methyl paraben, sodium propyl paraben, methyl p-hydroxybenzoate, propyl p-hydroxy benzoate and/or sorbic acid, suitably in an amount of from about 0.01% to about 1% by weight of the composition;

sequestering agents such as ethylenediamine tetraacetic acid and/or salts thereof, suitably in an amount of from about 0.005% to about 0.5% by weight of the composition;

vitamins, such as biotin, suitably in an amount of from about 0.01% to about 1.0% by weight of the composition;

pearlising agents such as stearic monoethanolamide, suitably in an amount of from about 0.01% to about 10% by weight of the composition.

emollients such as isopropyl myristate and/or a triglyceride of a fatty acid (e.g. lauric triglyceride and/or capric / caprylic triglyceride);

humectants such as glycerin and/or 1,3-butylene-glycol;

antioxidants such as vitamin C, d,l-α-tocopheryl acetate, butylated hydroxy-toluene, parabens, butylated hydroxy toluene, butylated hydroxyannisole, propyl-p-hydroxybenzoate and/or other suitable preservatives;

emulsion stabilisers, such as suitable salts, for example sodium chloride, sodium citrate and/or magnesium sulphate;

film formers to assist spreading on the surface of the skin such as alkylated polyvinyl-pyrrolidone;

perfumes suitably in an amount of from about 0.01% to about 2% by weight of the composition;

colourings, such as water soluble dyes such as tartrazine, suitably in an amount of from about a trace amount (such as 1×10^{-5} %) to about 0.1% by weight of the composition; and

other suitable agents such as thickening agents, gelling agents, gloss modifiers, texture modifiers, soothing agents, conditioners, moisturisers and sunscreen agents.

A further aspect of the invention comprises a method of preparing an anhydrous and/or hydrophobic composition for non-oral application comprising the steps of:

(a) spray drying a liquid to form a powder, the liquid comprising water-absorbent matrix and optionally at least one active ingredient which is incompatible with an anhydrous and/or hydrophobic composition when added directly; and

(b) mixing in a suitable manner the resulting powder with an acceptable diluent or carrier to form an anhydrous and/or hydrophobic composition suitable for administration by a non-oral route.

Further steps in the method of the invention are known to those skilled in the art. For example the powder may be brought into association with suitable inert diluents, carriers and/or any other optional ingredients (for example those described herein). The ingredients in the composition may be uniformly and/or intimately admixed and the resultant composition, if solid, may be shaped (for example by compressing and/or moulding). If the composition contains large amounts of excipients in relation to the spray-dried powder of the invention, repeated conventional mixing operations may be required to distribute the powder evenly and/or homogenously throughout the composition. The compositions may also be prepared in a manner known to those skilled in the art, to give a controlled release, for example rapid release or sustained release, of any active ingredient. Preferred methods of preparation are described in the Examples.

The invention will be understood with reference to the non-limiting Examples described below.

With the exception of the spray-dried powder of the invention (as described in Examples 1 to 3), the other ingredients used in the following Examples are largely conventional. In some of these Examples only the general type of each ingredient has been indicated as the specific ingredient can be any suitable conventional ingredient of the specified general type (for example any of those described above). These would be well known to a skilled formulator. It is not believed that the choice of a specific conventional ingredient would significantly

effect the advantageous properties of these Examples as far as they relate to the invention.

Example 1

(Spray-dried powder of a moisture cream)

Ingredient	*Amount (% w/w)*
Vegetable glycerine	1.73
1,3-Butylene glycol	3.46
Keltrol (thickener)	0.34
Sequestrene NA4 (powder)	0.05
Monostearin NSE (edible oil)	2.88
Polawax GP 200 (vegetable grade oil)	4.03
Cetyl alcohol (oil)	1.85
Hard paraffin (oil)	2.88
White spot paraffin (oil)	2.88
Light liquid paraffin (oil)	4.03
Silicone fluid F111/100 (oil)	1.15
Cetiol SN (oil)	5.76
Light colour wheat-germ oil	0.34
Pisane ® (protein isolate from yellow peas)	6.71
Maltodextrin (powder)	58.94
D,L-α-Tocopheryl acetate (oil)	0.12
D-Panthenol (moisturiser)	0.58
Oil of orchids	0.28
Lactic acid	0.03
Sodium lactate (60% aq. solution)	0.07

A powder of Sequestrene NA4 and Pisane ® was dispersed in water at 70 - 75 °C with a Silverson high shear mixer. The mass ratio of powder to water was 1:1.67 respectively. The vegetable glycerine, butylene glycol and Keltrol

were mixed together to from a slurry which was then added to the Pisane ® suspension. The oils were melted together at 70 - 75 °C and the aqueous slurry was added to this melt to form an emulsion. The maltrodextrin powder was mixed into to the emulsion with a Silverson high shear mixer. The panthenol, lactic acid and sodium lactate were added to the emulsion which was then homogenised with a Monton-Gaulin homogeniser at a pressure of 150 bar and at 75 °C. The emulsion was fed into a spray-dryer at an input temperature of 160 °C and an output temperature of 82 °C to produce a powder which was collected from the bottom of the cyclone of the spray-dryer.

Example 2

(Spray-dried powder)

Ingredient	*Amount (% w/w)*
Sequestrene NA4 (powder)	0.05
Polawax GP 200 (vegetable grade oil)	4.95
Cithrol GMS (emulsifier)	6.60
Cetyl alcohol (oil)	3.30
Light liquid paraffin (oil)	16.49
Silicone fluid (oil)	0.82
Pisane ® (protein isolate from yellow peas)	12.55
Maltodextrin (powder)	55.10

A powder of Sequestrene NA4 and Pisane ® was dispersed in water at 70 - 75 °C with a Silverson high shear mixer. The mass ratio of powder to water was 1:1.67 respectively. The oils were melted together at 70 - 75 °C and this oily melt was added to the aqueous mixture to form an emulsion. The maltrodextrin powder was mixed into to the emulsion with a Silverson high shear mixer. The emulsion was then homogenised with a Monton-Gaulin homogeniser at a pressure of 150 bar and at 80 °C. The emulsion was fed into a spray-dryer at an input temperature of 180 °C and an output temperature of

85 °C to produce a powder which was collected from the bottom of the cyclone of the spray-dryer.

Example 3

(Spray-dried powder of a moisturising lotion)

Ingredient	*Amount (% w/w)*
1,3-Butylene glycol (moisturiser)	3.87
Polawax GP 200 (vegetable grade oil)	4.83
White soft paraffin (oil)	12.36
Silicone fluid F111/100 (oil)	1.47
Cetyl alcohol (oil)	2.22
Hard paraffin (oil)	4.15
Light liquid paraffin (oil)	14.48
Monostearin NSE (edible oil)	3.48
Carboxymethyl cellulose gum (thickener)	0.40
Titanium dioxide sunscreen	2.76
Pisane ® (protein isolate from yellow peas)	10.00
Maltodextrin (powder)	37.22

The Pisane ® and the titanium dioxide were dispersed in water at 70 - 75 °C with a Silverson high shear mixer to from a suspension. The mass ratio of powder to water was 1:1.67 respectively. The butylene glycol and cellulose gum were mixed together to from a slurry which was then added to the aqueous suspension. The oils were melted together at 70 - 75 °C and the oily melt was added to the aqueous suspension. This mixture was then mixed with a Silverson high shear mixer. The maltrodextrin powder was added to the mixture using a Silverson high shear mixer. The mixture was homogenised with a Monton-Gaulin homogeniser at a pressure of 150 bar and at 80 °C. The homogenised mixture was fed into a spray-dryer with an input temperature of

160 °C and an output temperature of 80 °C to produce a powder which was collected from the bottom of the cyclone of the spray-dryer.

Example 4

(Medium translucent, pressed powder cosmetic with 50% spray-dried moisturising powder)

Ingredient	*Amount (% w/w)*
Sterilised Mistron Galaxy Talc (powder)	20.26
Sterilised Talc 120 (powder)	20.26
Magnesium stearate (lubricant, powder)	5.00
Pigment (powder)	2.64
Spray-dried moisturising powder (Ex. 1)	50.0
White liquid paraffin	1.05
Soft paraffin	0.70
Preservative (powder)	0.10

The spray-dried moisturising powder was prepared as described in Example 1 above.

All the ingredients except the paraffins were mixed together in a kitchen-type blender for ten minutes to form a powder mixture. The paraffins were melted together and this melt was sprayed into the powder mixture whilst the powder was being mixed. The powder was mixed for a further 5 minutes to ensure homogeneity. The resultant composition was milled using a hammer mill and then compressed into moulds to form a product.

Example 5

(Medium translucent, pressed powder cosmetic with 25% spray-dried moisturising powder)

Ingredient	*Amount (% w/w)*
Sterilised Mistron Galaxy Talc (powder)	32.56
Sterilised Talc 120 (powder)	32.56
Magnesium stearate (lubricant, powder)	5.00
Pigment (powder)	2.24
Spray-dried moisturising powder (Ex. 1)	25.0
Liquid paraffin	1.58
White soft paraffin	0.14

This composition was prepared in a similar manner to Example 4.

Example 6

(Medium translucent, pressed powder cosmetic with 10% spray-dried moisturising powder)

Ingredient	*Amount (% w/w)*
Sterilised Mistron Galaxy Talc (powder)	41.21
Sterilised Talc 120 (powder)	41.21
Magnesium stearate (lubricant, powder)	5.00
Pigment (powder)	2.24
Spray-dried moisturising powder (Ex. 1)	10.00
Liquid paraffin	0.21
White soft paraffin	0.14

This composition was prepared in a similar manner to Example 4.

Example A

(Medium translucent, pressed powder cosmetic - control for Examples 4 to 6)

Ingredient	*Amount (% w/w)*
Sterilised Mistron Galaxy Talc (powder)	44.58
Sterilised Talc 120 (powder)	44.58
Magnesium stearate (lubricant, powder)	5.00
Pigment (powder)	2.24
Liquid paraffin	2.10
White soft paraffin	1.40
Preservative (powder)	0.10

This composition was prepared in a similar manner to Example 4. Example 7 does not contain a spray-dried powder but is a comparison for Examples 4 to 6.

The properties of Examples 4 to 6 were compared with A. Example A without the spray-dried powder of Example 1 was a very light talc powder which had a powdery feel on the skin. Examples 4 to 6 had increasingly more creamy and emollient properties and a heavier feel on the skin the more of Example 1 they contained.

Example 7

(Lipstick with a spray-dried moisturising powder)

Ingredient	*Amount (% w/w)*
Plant wax	6.26
Mineral wax	9.00
Fatty alcohol	22.87
Synthetic fat	10.00
Preservative	0.10
Anti-oxidant	0.03

25 % Pigment in castor oil paste	34.99
Spray-dried moisturising powder (Ex. 3) in oil	4.00
Butylene glycol	1.50
Castor oil	11.25

The spray-dried moisturising powder was prepared as described in Example 3 and mixed into a castor oil base at a respective mass ratio of 1:3 powder to oil.

The pigment, spray-powder, butylene glycol and castor oil were mixed together to form a uniform paste. The remaining ingredients were added and the mixture was then melted together at 78 °C and poured into moulds to form a product.

A comparative example, Example B, was prepared as above omitting the spray-dried powder of Example 3.

To the volar aspect of the forearm of forty volunteers, two sites were delineated, one to which the lipstick of Example 7 was applied and the other to which Example B was applied as a control. Each lipstick was weighed before and after application to determine the mass of lipstick that had been applied to the skin. The mean amount of Example B applied to the skin of each subject was approximately 5.90 mg. The mean amount of Example 7 applied to the skin of each subject was approximately 7.24 mg. This represents a mean increase of approximately 22.7 % in the mass of lipstick delivered to the skin per subject for Example 7 over the control (Example B). The data are statistically significant.

Thus Example 7, which comprises the spray-powder of Example 3, exhibits improved topical delivery of lipstick compared to the formulation without the powder.

Example 8

(Bath salts with spray-dried moisturising powder)

Ingredient	*Amount (% w/w)*
Sodium sequicarbonate (powder)	87.24
Pigment	0.01
PEG 7 glyceryl cocoate	0.25
Perfume	0.40
Anionic surfactant	2.00
Silica powder	0.10
Spray-dried moisturising powder (Ex. 2)	20.00

The spray-dried moisturising powder, which was prepared as described in Example 2, was mixed with the sodium sequcarbonate and silica powders in a kitchen blender. To this powder mixture was added the PEG 7 glyceryl cocoate, anionic surfactant, pigment and perfume to form a bath salt product with moisturising properties.

Example 9

(Boots super-absorbent foot powder with spray-dried moisturising powder)

Ingredient	*Amount (% w/w)*
Sanitised talc	69.10
Spray-dried moisturising powder (Ex. 2)	29.80
Tricalcium phosphate	0.50
Triclosan (biocide & deodorant)	0.01
Perfume	qs

The spray-dried moisturising powder, which was prepared as described in Example 2, was mixed with the tricalcium phosphate in a high speed blender. The talc was added followed by the triclosan and the mixture was mixed for ten

minutes. The perfume was added slowly whilst the mixture was being mixed to form a foot powder with moisturising properties.

Example 10

(Talc with 10 % spray-dried moisturising powder)

Ingredient	*Amount (% w/w)*
Spray-dried moisturising powder (Ex. 2)	10.00
Tricalcium phosphate	0.50
Talc	89.50
Perfume	0.20

The spray-dried moisturising powder, which was prepared as described in Example 2, was mixed with the tricalcium phosphate in a blender to unclump the powder. The talc was added and the mixture was mixed for ten minutes. The perfume was sprayed into the mixture to form a talcum powder with moisturising properties.

Example 11

(Shaving soap with spray-dried moisturising powder)

Ingredient	*Amount (% w/w)*
Shaving soap noodles	to 100
Pigmentary titanium dioxide	0.10
Optical brightener	0.01
Perfume	0.99
Spray-dried moisturising powder (Ex. 1)	10.00

The spray-dried moisturising powder was prepared as described in Example 1. The above ingredients were mixed together thoroughly and compressed into a moulds to form a soap with moisturising properties.

Example 12

(Deodorant stick with spray-dried moisturising powder)

Ingredient	*Amount (% w/w)*
Stearyl alcohol vegetable grade	13.13
Hydrogenated castor oil	5.05
Cyclomethicone	50.50
Aluminium chlorohydrate	20.20
Silica thickener	1.01
Sterilised Mistron Galaxy Talc	9.09
Mixture of glyceryl stearate and PEG-100 stearate	1.01
Butylated hydroxy toulene	0.01
Oily herbal extracts	0.20
Perfume	0.50
Spray-dried moisturising powder (Ex. 2)	1.50

The spray-dried moisturising powder was prepared as described in Example 2.

The stearate mixture, castor oil and stearyl alcohol were melted together. In a separate container the aluminium chlorohydrate and silica thickener were added to the cyclomethicone using a Silverson high shear mixer. The two mixtures were then mixed together and heated to 75 - 80 °C. The talc and butylated hydroxy toulene were added to the resultant mixture whilst it was being stirred. The mixture was stirred with a Silverson high shear mixer to ensure it was homogenous and then cooled to 75 °C whilst being stirred. The herbal extract and perfume were added and the mixture was compressed. Finally the composition was poured into suitable packaging and allowed to cool to ambient temperature to form a deodorant with moisturising properties.

Example 13

(Anti-perspirant stick with spray-dried moisturising powder)

Ingredient	*Amount (% w/w)*
Cyclomethicone	52.00
Aluminium chlorohydrate	17.00
Silica thickener	1.00
Stearyl alcohol vegetable grade	13.00
Hydrogenated castor oil	5.00
Perfume	0.50
Butylated hydroxy toulene	0.01
Sterilised Mistron Galaxy Talc	11.00
Spray-dried moisturising powder (Ex. 2)	1.50

This Example was prepared in a similar manner to Example 12.

Example 14

(Sunstick of SPF 20 with 1.5 % spray-dried moisturising powder)

Ingredient	*Amount (% w/w)*
Zinc oxide sunscreen in a synthetic ester paste	38.57
Titanium dioxide sunscreen (coated with Al stearate) in a plant oil paste	13.33
Mineral wax	13.03
Plant wax	5.52
Plant oil	11.89
Synthetic fat	6.59
Synthetic ester	11.22
Alpha bisabolbol (soothing agent)	0.12
Spray-dried moisturising powder (Ex. 2)	1.50

The spray-dried moisturising powder was prepared as described in Example 2.

The above ingredients were melted together and then mixed with a Silverson high shear mixer to obtain a homogenous mixture. The mixture was poured into moulds to form a sunstick with moisturising properties.

Example 15

(Sunstick for sensitive skin of SPF 25 with 1 % spray-dried moisturising powder)

Ingredient	*Amount (% w/w)*
Titanium dioxide sunscreen (coated with Al stearate) in a plant oil paste	21.70
Titanium dioxide sunscreen in a plant oil paste	10.00
Octyl methoxycinnamate (organic sunscreen)	5.00
Butyl methyldibenzoylmethane (organic sunscreen)	2.50
Mineral wax	14.40
Plant wax	5.66
Synthetic ester	32.98
Synthetic fat	6.76
Spray-dried moisturising powder (Ex. 3)	1.00

The spray-dried moisturising powder was prepared as described in Example 3.

All the ingredients were mixed together apart from the organic sunscreens. The mixture was then heated until it melted and was mixed with a Silverson high shear mixer. The remaining ingredients were added to this mixture which was heated and then poured into moulds to form a sunstick with moisturising properties.

Example 16

(Sunstick for sensitive skin of SPF 25 with 1.5% spray-dried moisturising powder)

Ingredient	*Amount (% w/w)*
Titanium dioxide sunscreen (coated with Al stearate) in a plant oil paste	21.70
Titanium dioxide sunscreen in a plant oil paste	10.00
Octylmethoxycinnamate (organic sunscreen)	5.00
Butylmethyldibenzoylmethane (organic sunscreen)	2.50
Mineral wax	14.4
Plant wax	5.66
Synthetic ester	32.98
Synthetic fat	6.76
Spray-dried moisturising powder (Ex. 3)	1.00

This Example was prepared in a similar manner to Example 15.

Example 17

(Sunstick for sensitive skin of SPF 25 with 2 % spray-dried moisturising powder)

Ingredient	*Amount (% w/w)*
Titanium dioxide sunscreen (coated with Al stearate) in a plant oil paste	21.70
Titanium dioxide sunscreen in a plant oil paste	10.00
Octylmethoxycinnamate (organic sunscreen)	5.00
Butylmethyldibenzoylmethane (organic sunscreen)	2.50
Mineral wax	14.17
Plant wax	5.56
Synthetic ester	32.43
Synthetic fat	6.64
Spray-dried moisturising powder (Ex. 3)	2.00

This Example was prepared in a similar manner to Example 16.

Example 18

(Sunstick for sensitive skin of SPF 25 with 5 % spray-dried moisturising powder)

Ingredient	*Amount (% w/w)*
Titanium dioxide sunscreen (coated with Al stearate) in a plant oil paste	21.70
Titanium dioxide sunscreen in a plant oil paste	10.00
Octyl methoxycinnamate (organic sunscreen)	5.00
Butylmethyldibenzoylmethane (organic sunscreen)	2.50
Mineral wax	13.52
Plant wax	5.23
Synthetic ester	30.77
Synthetic fat	6.31
Spray-dried moisturising powder (Ex. 3)	5.00

This Example was prepared in a similar manner to Example 15.

Example 19

(Lipstick with a spray-dried powder)

Ingredient	*Amount (% w/w)*
Wax	22.46
Castor oil	0.66
Synthetic fat	11.74
Silicone fluid (oil)	40.96
Fatty alcohol	0.71
1,3 Butylene glycol	0.99
Pigment in oil paste	13.45
Pearlising agent	4.56

Rosehip oil	0.50
d,l-α-Tocopheryl acetate	0.99
Octyl methoxycinnamate (organic sunscreen)	0.99
Butyl methyl dibenzoyl methane (organic sunscreen)	0.50
Polyquaternium 37 (cationic resin)	0.50
Spray-dried moisturising powder (Ex. 2) in oil	1.00

The spray-dried powder was prepared as described in Example 2 and mixed into a castor oil base at a respective mass ratio of 1:3 powder to oil.

The pigment, spray-powder, butylene glycol and castor oil were mixed together to form a uniform paste. The remaining ingredients were added and the mixture was then melted together at 78 °C and poured into moulds to form a product.

A comparative example, Example C, was prepared as above omitting the spray-dried powder ingredient.

To the volar aspect of the forearm of forty volunteers, two sites were delineated, one to which the lipstick of Example 19 was applied and the other to which the Example C was applied as a control. Each lipstick was weighed before and after application to determine the mass of lipstick that had been applied to the skin. The mean amount of Example C applied to the skin of each subject was approximately 0.98 mg. The mean amount of Example 20 applied to the skin of each subject was approximately 1.11 mg. This represents a mean increase of approximately 13 % in the mass of lipstick delivered to the skin per subject for Example 19 over the control (Example C).

Thus Example 19, which comprises the spray-powder of the invention, exhibits improved topical delivery of lipstick compared to the formulation without the powder.

Example 20

Nail enamel with 0.25% spray dried moisture cream

Ingredient	%
Standard nail polish base + 0.25% spray dried moisture cream	89.65
Calcium fibres	0.11
Pearl suspension	0.28
D&C red No 6 dispersion	6.57
D&C Red No 34 dispersion	2.07
TiO_2 dispersion	1.32

Calcium fibres were added to a small tub containing the standard nail polish base and the spray dried powder (which was prepared as described in Example 2). Then the mixture was stirred until the components were evenly distributed. Pearl suspension was then mixed into this blend until fully integrated. D&C Red No 6 dispersion, D&C Red No 34 dispersion and TiO_2 dispersion were added to the mixture, which was stirred until all the ingredients were evenly dispersed. The material was then bottled and sealed.

Example 21

Nail enamel with 0.5% nail spray dried moisture cream

Ingredient	%
Standard nail polish base + 0.5% spray dried powder	89.68
Calcium fibres	0.11
Pearl suspension	0.28

TiO_2 dispersion	1.31
D&C Red No 34 dispersion	2.07
D&C Red No 6 dispersion	6.55

Calcium fibres were added to a small tub containing the standard nail polish base and 0.5% spray dried powder (which was prepared as described in Example 2), Then the mixture was stirred until the components were evenly distributed. Pearl suspension was then mixed into this blend until fully integrated. TiO_2 dispersion, D&C Red No 34 dispersion and D&C Red No 6 dispersion were added to the mixture, which was stirred until all ingredient were evenly dispersed. The material was then bottled and sealed.

Example 22

Nail enamel with 0.75% spray dried moisture cream

Ingredient	%
Standard nail polish base + 0.75% spray dried moisture cream	89.70
Calcium fibres	0.11
Pearl suspension	0.28
D&C Red No 6 dispersion	6.54
D&C Red No 34 dispersion	2.06
TiO_2 dispersion	1.31

Calcium fibres were added to a small tub containing the Standard nail polish base and 0.75% spray dried moisture cream (which was prepared as described in Example 2), then the mixture was stirred until the components were evenly distributed. Pearl suspension was then mixed into this blend until fully integrated. D&C Red No 6 dispersion, D&C Red No 34 dispersion and

TiO_2 dispersion were added to the mixture, which was stirred until all the ingredients were evenly dispersed. The material was then bottled and sealed.

Example 23

Eyeshadow and 1% spray dried moisture cream

Ingredient	%
Silica	0.10
Iron oxide yellow	0.77
Cosmetic black	6.80
Ultramarine blue	11.65
Flamenco ultrasilk	5.00
Calflo	0.80
Nylon-12	10.00
Sanitised talc	49.88
Silicone fluid F111/20	5.00
Pearl powder	10.00
Spray dried moisture cream	1.00

Spray dried moisture cream (prepared as described in Example 2) and silica, iron oxide yellow, cosmetic black, ultramarine blue, flamenco ultrasilk, calflo, nylon-12 and sanitised talc were charged to a mixer, and stirred together at high speed for 10 minutes. Silicone fluid F111/20 was sprayed into the slowly stirred material which was then mixed at high speed for 20 minutes. Pearl powder was then added to the slowly stirred mixture, which was then stirred for a further minute. The resulting mixture was then sieved through a 30 mesh sieve to give the product.

Example 24

Blush perfect and 1% spray dried moisture cream

Ingredient	%
Cosmetic black	0.20
Magnesium stearate	1.60
Low lustre pigment	0.10
Polyethylene wax	10.00
Natural silk powder	0.20
Titanium dioxide	0.10
Sanitised talc	75.06
Cosmetic Russet	0.15
Cosmetic Red	2.93
Octyl methoxycinnamate	0.66
Phenyll trimethicone	2.25
Eutanol G	1.10
Almond oil	1.00
Propylene glycol	0.20
1,3-butylene glycol	0.20
DL-A-Tocopheryl acetate	0.20
Borage oil	0.05
Pearl powder	4.00
Spray-dried moisture cream	1.00

Spray-dried moisture cream (prepared as described in Example 2) and cosmetic black, magnesium stearate, low lustre pigment, polyethylene wax, natural silk powder, titanium dioxide, sanitised talc, cosmetic russet, and cosmetic red were charged to a mixer, and stirred together at high speed for 10 minutes. Octyl methoxycinnamate, phenyl trimethicone, Eutanol G, almond oil, propylene glycol, 1,3-butylene glycol, DL-A-Tocopheryl acetate and borage oil

were sprayed into the slowly stirred material which was then mixed at high speed for 10 minutes. Pearl powder was then added to the slowly stirred mixture, which was then stirred for a further two minutes. The resulting mixture was then sieved through a 30 mesh sieve to give the product.

Example 25

Pressed powder and 1% spray dried moisture cream

Ingredient	%
Yellow iron oxide	0.54
Red iron oxide	0.24
Natural silk powder	0.10
Mica/Silica	0.10
Titanium dioxide	0.10
Flamenco ultrasilk	2.00
Sericite	5.00
Nylon-12	0.10
Irrad talc	83.82
Borage oil	0.10
DL-A-Tocopheryl acetate	0.10
1,3-butylene glycol	0.10
Propylene glycol BP	0.10
Liquid paraffin BP	3.80
Phenyl trimethicone	3.80
Spray-dried moisture cream	1.00

Spray-dried moisture cream (prepared as described in Example 2) and Yellow iron oxide, red iron oxide, natural silk powder, mica/silica, titanium dioxide, flamenco ultrasilk, sericite, nylon-12 and irrad talc were charged to a mixer, and stirred together at high speed for 10 minutes. Borage oil,

DL-A-Tocopheryl acetate, 1,3-butylene glycol, propylene glycol BP, liquid paraffin BP and phenyl trimethicone were sprayed onto the slowly stirred material which was then mixed at high speed for 5 minutes. The resulting mixture was passed through a hammer mill then sieved through a 30 mesh sieve to give the product.

Example 26

Protective loose powder - transulcent (control) and 1% spray dried powder

Ingredient	%
Titanium dioxide	0.10
Aluminium starch octenyl succinate	79.76
Cosmetic ebony	0.02
Cosmetic yellow	0.22
Nylon-12	1.76
Micra/silica	0.10
Spray-dried moisture cream	1.00
Natural silk powder	0.10
Yeast peptides powder	1.00
Calflo	0.24
Red iron oxide	0.10
Phenyl trimethicone	0.30
DL-A-tocopheryl acetate	0.10
1,3-butylene glycol	0.10
Propylene glycol BP	0.10
Bismuth oxychloride	15.00

Spray-dried moisture cream (prepared as described in Example 2) and titanium dioxide, aluminium starch octenyl succinate, cosmetic ebony, cosmetic yellow, nylon-12, micra/silica and natural silk powder, yeast peptides powder,

calflo, red iron oxide and bismuth oxychloride were charged to a mixer, and stirred together at high speed for 15 minutes. Phenyl trimethicone, DL-A-totopheryl acetate, 1,3-butylene glycol and propylene glycol BP was sprayed into the slowly stirred material which was then mixed at high speed for 10 minutes. The resulting mixture was then sieved through a 30 mesh sieve to give the product.

Example 27

Conditioner (for hair)

Ingredient	%
Pectin	0.70
Cationic derivative of hydroxypropyl guar	0.20
Arginina PCA	0.50
Maltodextrin	83.3
Spray dried moisture cream	10.00
Yucca extract	2.00
Betaine	0.50
D-L panthenol	0.30
Albumen	0.50
Acrylates/VA crosspolymer	1.00
Distearyldimonium chloride	1.00

Pectin, cationic derivative of hydroxypropyl guar, arginina PCA, maltodextrin and spray-dried moisture cream (which was prepared as described in Example 2) were mixed together using a silverson high shear mixer. To the stirred mixture was added sequentially yucca extract, betaine, D-L-panthenol, albumen, acrylates/VA crosspolymer and distearyldimonium chloride. The resultant mixture was then stirred until it gave a homogeneous product.

Example 28

Lip pencil - softly red (spray dried moisture cream)

Ingredient	%
Microcrystalline wax	14.56
Carnauba wax	53.36
D&C red No 7 calcium lake	6.76
Titanium dioxide	2.51
F D&C yellow No 5 aluminium lake	7.52
D&C red No 6 barium lake	4.46
Iron oxides	1.67
Sorbitan tristearate	3.00
BHA	0.03
Spray-dried moisture cream	0.50

The microcrystalline wax and carnauba wax were mixed together and heated to 120°C. D&C red No 7 calcium lake, titanium dioxide, F D&C yellow No 5 aluminium lake, D&C red No 6 barium lake, iron oxides, sorbitan tristearate,BHA and spray-dried moisture cream (which was prepaed as described in Example 2) were then dispersed in the oil using a silverson high shear mixer. The mixture was then poured into moulds, then left to stand for a few days to form the hardened pencil lead.

Example 29

Eye pencil brown (spray dried moisture cream)

Ingredient	%
Japan wax	6.75
Hydrogenated palm kernel oil	13.00
Carnauba wax	9.62
Hydrogenated coco-glycerides	27.23
Hydrogenated castor oil	3.38
Candelilla wax	6.74
Iron oxides	30.75
Silica	0.50
Sorbitan tristearate	3
BHA	
Spray-dried moisture cream	0.50

The Japan wax, hydrogenated palm kernel oil, carnauba was, hydrogenated castor oil and candelilla wax were mixed together and heated to 12°C. Hydrogenated coco-glycerides, iron oxides, silica, sorbitan tristearate, BHA and spray-dried moisture cream were then dispersed in the oil using a silverson high shear mixer. The mixture was then poured into moulds, then left to stand for a few days to form the hardened pencil lead.

CLAIMS

1. An spray-dried powder compatible with an anhydrous and/or hydrophobic non-oral composition, the powder comprising a substantially water-soluble absorbent matrix containing at least one protein and at least one hydrolysed starch.

2. A powder as claimed in claim 1, in which the ratio by weight of protein to hydrolysed starch is in the range 1:20 to 1:2.

3. A powder as claimed in claim 1, in which the ratio by weight of protein to hydrolysed starch is in the range 1:10 to 1:4.

4. A powder as claimed in claim 3, in which the matrix comprises starch casein, protein of the type obtained from plants and/or any compatible mixture and/or derivative thereof.

5. A powder as claimed in claim 4, in which the protein is of the type obtained from seeds.

6. A powder as claimed in either claim 4 or 5, in which the protein is of the type obtained from legumes.

7. A powder as claimed in claim 6, in which the matrix comprises a protein is obtained from peas and/or soya beans.

8. A powder as claimed in claim 7, in which the protein is of the type obtained from yellow peas.

9. A powder as claimed in any one of the preceding claims wherein the hydrolysed starch has a molecular weight in the range 1,000 to 100,000.

10. A powder as claimed in any preceding claim, in which the hydrolysed starch is maltodextrin, hydrolysed potato derivative, hydrolysed corn derivative, hydrolysed maize derivative, hydrolysed oat derivative, hydrolysed tapioca derivative, cyclodextrin, dextrin (from corn tapioca etc), pullulan and cellulose derivatives.

11. A powder as claimed in any one of the preceding claims in which the hydrolysed starch is maltodextrin having a molecular weight in the range 1,000 to 10,000.

12. A powder as claimed any preceding claim, which further comprises a surfactant.

13. A powder as claimed any preceding claim, which further comprises one or more pharmaceutical active ingredients, cosmetic active ingredient, toiletries active ingredient and/or any compatible mixture thereof.

14. A substantially anhydrous and/or hydrophobic composition for non-oral application comprising a spray-dried powder as claimed in any preceding claim.

15. A composition as claimed in claim 12, which is suitable for topical application.

16. A composition as claimed in claim 14 or 15 containing 0.1 to 60% by weight of the spray dried powder.

17. A method of preparing a substantially anhydrous and/or hydrophobic composition for non-oral administration as claimed in claim 14 or 16, comprising the steps of:

(a) spray drying a liquid to form a powder as claimed in any of claims 1 to 13; and

(b) mixing the powder in a suitable manner with other suitable ingredients to form an anhydrous and/or hydrophobic composition suitable for administration by a non-oral route.

INTERNATIONAL SEARCH REPORT

Inte ional Application No
PCT/EP 97/06056

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61K7/035 A61K7/48

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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X	WO 94 01001 A (DANOCHEMO AS ;SKELBAEK TOVE (DK); ANDERSEN STEEN (DK)) 20 January 1994 see claims 1,4,7,9; example 2 ---	1-4, 9-11,13
X	CHEMICAL ABSTRACTS, vol. 114, no. 14, 8 April 1991 Columbus, Ohio, US; abstract no. 129150, XP002060446 see abstract & JP 02 264 721 A (TAMA BIOCHEMICAL CO.) 29 October 1990 ---	1,2,4,9, 10, 12-15,17
	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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2

Date of the actual completion of the international search	Date of mailing of the international search report
27 March 1998	14/04/1998

Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

Inte tional Application No
PCT/EP 97/06056

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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INTERNATIONAL SEARCH REPORT

information on patent family members

Inte ional Application No
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